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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,632	04/07/1999	PETER MICHAEL WATERHOUSE	021565-060	6526

21839 7590 03/30/2012

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POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
03/30/2012	ELECTRONIC

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PETER MICHAEL WATERHOUSE,
MING-BO WANG, and MICHAEL WAYNE GRAHAM

Appeal 2011-002275
Application 09/287,632
Technology Center 1635

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 by the Patent Applicant from the Patent Examiner's rejections of claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109 and 115-122 in U.S. Application 09/287,632 ("the '632 application"). The Board's jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The pending claims in this appeal are directed to a chimeric DNA molecule which comprises complementary sense and antisense nucleotide sequences that, when transcribed into the RNA, form an RNA hairpin structure. The complementary sequences are obtained from a nucleic acid of interest. A hairpin is a double-stranded or duplex[1] RNA structure comprising a stem and loop, where the stem is a double-stranded region formed by two complementary nucleotide sequences hybridized together (the sense and antisense sequences) and the loop is an unpaired single-stranded region between the two complementary sequences that joins them together. The entire RNA structure resembles a hairpin used to hold hair in place. The hairpin RNA structure, when expressed in a plant cell, reduces phenotypic expression of a nucleic acid of interest, such as an endogenous gene. For example, if it is desired to reduce expression of a plant desaturase in order to modify the plant's fatty acid content, a chimeric DNA encoding a RNA hairpin structure comprising desaturase sequences is introduced into the plant cell (Spec. 13:11-27).

Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109, and 115-122 are pending and stand rejected by the Examiner as follows:

1. Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109, and 115-122 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

2. Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109, and 115-122 under 35 U.S.C. 103(a) as being unpatentable over Fire (US 6,506,559) in view of Brown (US 5,859,347), Lusky (US 6,350,575), and Schiedner

[1] The terms "double-stranded" and "duplex" are used interchangeably.

(*Nature Genetics*, 18:180-83, 1998), the combination in view of Baracchini (US 5,801,154).

3. Claims 22, 26, 42, 53-54, 56, 58, 63-69, 100-103, 109, and 115-122 under 35 U.S.C. 103(a) as being unpatentable over Flavell (*Proc. Natl. Acad. Sci.*, 91:3490-96, 1994), Metzlaff (*Cell*, 88:845-54, 1997) and Stam (*Annals of Botany*, 79:3-12,1997), the combination in view of Brown (US 5,859,347), and Lusky (US 6,350,575).

4. Claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109, and 115-122, provisionally rejected under the doctrine of obviousness type double patenting over pending claims 35-38 of U.S. Patent Application No. 11/841,737 (App. Br. 43; Examiner's Answer listed cancelled claims).

Claim 22 is representative and reads as follows:

> A plant cell, comprising a nucleic acid of interest, which is normally capable of being phenotypically expressed, further comprising a chimeric DNA molecule comprising the following operably linked parts:
>
> a) a promoter, operative in said plant cell;
>
> b) a DNA region, which when transcribed, yields an RNA molecule with at least one RNA region with a nucleotide sequence comprising
>
> i) a sense nucleotide sequence including at least 20 consecutive nucleotides having 100% sequence identity with at least 20 consecutive nucleotides of the nucleotide sequence of the nucleic acid of interest; and
>
> ii) an antisense nucleotide sequence including at least 20 consecutive nucleotides having 100% sequence identity with the complement of said at least 20 consecutive nucleotides of said sense nucleotide sequence;
> wherein the RNA is capable of forming an artificial hairpin RNA structure with a double stranded RNA stem by base-pairing between the regions with sense and antisense nucleotide

sequence, and wherein said DNA region comprises an intron heterologous to said sense nucleotide sequence; and

c) a DNA region involved in transcription termination and polyadenylation.

(Appeal Brief, Claims Appendix 3-4.) An oral hearing was held on January 12, 2012. A transcript of the hearing has been entered into the record.

SECTION 112 REJECTION

All the independent claims in this appeal are drawn to DNA constructs with a DNA region comprising "a sense nucleotide sequence including at least 20 consecutive nucleotides" and a complementary "antisense nucleotide sequence including at least 20 consecutive nucleotides" of a "nucleic acid of interest." The construct comprises a promoter, an intron, and transcription termination and polyadenylation sequences. The Examiner found that the claims lacked written description support because the specification did not describe a representative number of species in the claimed genus, "e.g. the myriad of sequences encompassed by the genus intron, or intronic sequences is vast, and further whereby any intronic sequence is inserted anywhere within the DNA construct" to achieve the silencing activity (Answer 5).

The Examiner found that the application disclosed examples of complementary sense and antisense nucleotide sequences of 1580 and 620 base pairs, but not sequences of smaller size as encompassed by the claim (Answer 6-7). The Examiner also found that the art was unpredictable as evidenced by the declaration of Dr. Marc DeBlock (Answer 7-8). The Examiner stated that Applicants "did not have support, prior to Fire's disclosure, for the limitations instantly claimed, particularly with respect to

siRNA of lengths as short as 20 nucleotides in length per strand." (Answer 28.)

We shall reverse this rejection.

In setting forth the rationale as to why the claims do not comply with the written description requirement of 35 U.S.C. § 112, first paragraph, the Examiner cited *Univ. of Cali. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). *Lilly* involved the validity of claims drawn to novel cDNA sequences encoding vertebrate insulin and mammalian insulin. Despite the breadth of the claims, the Patentee had described only a single cDNA to rat insulin in the patent specification. *Lilly*, 119 F.3d at 1563, 1567. The claims were held invalid for failing to provide an adequate written description of the claimed genus.

> In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Lilly, 119 F.3d at 1568.

The facts of this case are different from *Lilly*. The claims at issue in this appeal are not directed to new or unknown biological materials as they were in the *Lilly* case. The claimed plant promoters, introns, and DNA sequences involved in transcription termination and polyadenylation are all classes of DNA materials that were widely known to persons of ordinary skill in the art at the time the application was filed. The patent application

specification discloses examples of such materials (Spec. 15:24-29; 23:7-15, 24:10-25; 36:10-11). Expert testimony was provided that introns were well-defined elements whose structural features were known to persons of ordinary skill prior to the application filing date (Declaration of Peter Robert Schofield, Ph.D., dated October 30, 2007, ¶¶13-26; Declaration of Elizabeth Salisbury Dennis, Ph.D., dated August 6, 2007, ¶¶11-17; App. Br. 17-21). The testimony also established that the placement of the intron was not critical and a skilled worker reading the Specification would have appreciated this (Declaration of Elizabeth Salisbury Dennis, Ph.D., ¶¶11 & 14; Declaration of Marc De Block, Ph.D., dated June 8, 2007, ¶¶13 & 15).

The Examiner stated that paragraph 14 of Dr. De Block's declaration reported "hairpin constructs that failed to provide a predictable phenotype of differences in flowering in oilseed rape, and depended on the insertion of a particular intron in a particular expression construct." (Answer 8.) We have reviewed paragraph 14 and while it reports differences in phenotypic expression, the claims do not require that a specific level of expression be achieved. Thus, we do not agree that such differences support the Examiner's conclusion that the claims lack written descriptive support.

In sum, the evidence does not support the Examiner's conclusion about the lack of written description support for the claimed class of intron sequences.

With regard to the DNA region comprising at least 20 consecutive nucleotides of sense and antisense sequences of a "nucleic acid of interest," the Specification defines a "nucleic acid of interest" to be "any particular RNA molecule or DNA sequence which may be present in a eucaryotic cell, particularly a plant cell." (Spec. 17:28-30.) The Specification does not

describe the "nucleic acid of interest" as novel, but rather describes the claimed methods and constructs as being useful to reduce expression of such nucleic acids (Spec. 8:5-9). It is therefore the constructs and methods of using them which are being asserted as novel, and not the nucleic acids of interest to which they are applied. The inventors do not assert to have invented a new genus of nucleic acids of interest. Rather, it is the method and constructs used in the method which are said to be new. It is unnecessary for a patent application to provide a description of nucleotide sequences which are already known in the prior art. *See Capon v. Eshhar*, 418 F.3d 1349, 1357-1358 (Fed. Cir. 2005); *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1367 (Fed. Cir. 2006).

The claim limitation of "20 consecutive nucleotides" is expressly described in the Specification (Spec. 21:5-7 & 23-26). An applicant complies with the written description requirement "by describing the invention, with all its claimed limitations." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (1997). It is unnecessary that actual working examples of hairpin RNA of 20 nucleotides be disclosed because the written description clearly describes such species within its ambit.

The facts of this case are similar to those *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003).

> More recently, in *Enzo Biochem*, we clarified that Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure. See *Enzo Biochem*, 296 F.3d at 1324, 63 USPQ2d at 1613. Both *Eli Lilly* and *Enzo Biochem* are inapposite to this case because the claim terms at issue here are not new or unknown biological

> materials that ordinarily skilled artisans would easily miscomprehend. Instead, the claims of Amgen's patents refer to types of cells that can be used to produce recombinant human EPO. Thus, TKT can only challenge the adequacy of disclosure of the vertebrate or mammalian host cell — not the human DNA itself. This difference alone sufficiently distinguishes *Eli Lilly*, because when used, as here, merely to identify types of cells (instead of undescribed, previously unknown DNA sequences), the words "vertebrate" and "mammalian" readily "convey[] distinguishing information concerning [their] identity" such that one of ordinary skill in the art could "visualize or recognize the identity of the members of the genus." *Eli Lilly*, 119 F.3d at 1567, 1568, 43 USPQ2d at 1406. [footnotes omitted.]

For the foregoing reasons, we concluded that the Examiner did not provide sufficient evidence to establish that the claimed subject matter does not comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, we reverse the rejection.

OBVIOUSNESS OVER FIRE

Under 37 C.F.R. § 1.131, an applicant for a patent can eliminate a publication as prior art by "establish[ing] invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based." In this case, the Examiner rejected the claims of the '632 application as obvious in view of the Fire patent and four additional prior art publications. Fire was filed on December 18, 1998 and claims benefit to a provisional application filed on December 23, 1997. The '632 application was filed April 7, 1999 and claims benefit to two provisional applications filed August 3, 1998 and April 8, 1998, respectively. Because the Fire patent was filed earlier and claims benefit to

provisional applications earlier than any of the earliest dates of the '632 application, the Fire patent is effective as prior art against the '632 application. To remove the Fire patent as prior art, Applicant filed a declaration by the inventors under 37 C.F.R. § 1.132 (hereinafter, "Decl.") to show that the claimed invention "was actually reduced to practice, prior to the December 23, 1997 filing date of U.S. provisional application No. 60/068,562 for which benefit is claimed by Fire." (App. Br. 31.)

The declaration showed evidence that chimeric DNA constructs had been made comprising:

• a) a promoter;

• b) a DNA region, that when transcribed into RNA, yielded an RNA with a sense nucleotide sequence and a complementary antisense nucleotide sequence; because of base-pairing between the complementary sense and antisense sequences, the RNA was capable of forming an artificial hairpin structure;

• an intron; and

• c) a region involved in transcription termination and polyadenylation.

Several DNA constructs were made, with complementary sense and antisense DNA regions of 750 base pairs (Decl. ¶15) and 558 base pairs (Decl. ¶¶21 & 38). The constructs, which were capable of forming artificial hairpin structures, were introduced into plants cells and shown to reduce target gene expression (Decl. ¶¶18, 31, & 39).

Regions a) through c) above correspond to a) through c) of the claimed DNA construct recited in all of the independent claims. Plant cells were transformed with the constructs as required by independent claims 22

and 100. Thus, the declaration established that constructs and plants cells within the scope of the claims had been made prior to the December 23, 1997 priority date of the Fire patent.

The claims also require that the sense and antisense sequences be of at least 20 consecutive nucleotides. The constructs made by the inventors, prior to December 23, 1997, comprise complementary sense and antisense sequences of 558 and 750 base pairs (Decl. ¶¶15, 21, & 38), are least 20 nucleotides in length, and thus are also within the scope of the claim.

The Examiner did not dispute that constructs within the scope of the claims had been reduced to practice prior to December 23, 1997, but contends:

> Applicant has not provided proper support for the short nucleobase size limitations of the instant claims, which are drawn to RNAi constructs comprising at least 20 nucleotides in length. Support has been provided for double stranded constructs comprising more than 550 nucleotides in length, but not comprising 20 nucleotides in length. For these reasons, the prior art of Fire still stands as valid prior art.

(Answer 10.)

In other words, the Examiner required that constructs comprising regions of 20 nucleotides to have been made by the inventors prior to the effective date of the Fire patent. We do not agree with the Examiner's analysis.

37 C.F.R. § 1.131 "provides an applicant a mechanism for overcoming specific prior art references predating his effective filing date. The applicant need show priority with respect to only so much of the claimed invention as the references disclose, *In re Stempel*, 44 CCPA 820, 826, 241 F.2d 755, 760, 113 USPQ 77, 81 (1957), or only so much as to

render the claimed invention obvious. *In re Spiller*, 500 F.2d 1170, 1177, 182 USPQ 614, 619 (CCPA 1974)." *In re Scheiber*, 587 F.2d 59, 61-62 (CCPA 1978).

In this case, Fire describes double-stranded RNA structures (such as the claimed hairpin) comprising nucleotide sequences "at least 25, 50, 100, 200, 300, or 400 bases." (Fire, col. 8, ll. 5-6.) The showing in the Inventor's declaration of constructs comprising double-stranded structures of 558 and 750 base pairs in length is as much shown in Fire since such structures are "at least 25, 50, 100, 200, 300, or 400 bases" in length.

The Examiner's requirement that an embodiment of "20 consecutive nucleotides" to have been made in order to show priority is not proper. As held in *Scheiber*, to eliminate a prior art publication as prior art, an applicant "need show priority with respect to only so much of the claimed invention as the references disclose." 59 F. 2d at 62. The Examiner did not establish that such requirement was not met, but rather argued that support for the "20 consecutive nucleotides" feature of the claims was necessary. While such requirement might be pertinent in determining whether the claim is in compliance with § 112, first paragraph, it is not applicable to a determination under 37 C.F.R. § 131.[2]

Accordingly, we conclude that Appellants' showing was sufficient to predate Fire. As the rejection was based on Fire's disclosure, and such disclosure is not prior art to the claimed invention, we reverse the rejection of claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109, and 115-122 under

[2] "Unlike Rule 131, §120 operates independently of the prior art, of which it makes no mention, and it expressly requires an earlier application to disclose the claimed subject matter in compliance with 35 USC 112, first paragraph." *In re Scheiber*, 199 U.S.P.Q. 782, 784 (Fed. Circ. 1978).

35 U.S.C. § 103(a) as obvious over Fire, Brown, Lusky, Schiedner, and Baracchini.

OBVIOUSNESS OVER FLAVELL, METZLAFF, & STAM

The Examiner found that each of Flavell, Metzlaff, and Stam described duplex RNA formed between sense and antisense fragments in gene silencing, providing a reason to have made a DNA construct capable of forming a duplex RNA of sense and antisense sequences in order to test their ability to inhibit gene expression of a known target gene (Answer 22-23). The Examiner acknowledged that neither Flavell, Metzlaff, nor Stam described an intron as recited in b) ii) of the claim, but found that the skilled worker would have included intron sequences to enhance expression as taught by Brown and Lusky (Answer 22 & 24).

With respect to Flavell, Metzlaff, and Stam, Applicant provided a declaration by Dr. Michael Metzlaff, an expert "in the field of the plant molecular biology, particularly the field of posttranscriptional gene silencing." (Metzlaff Decl. ¶ 2, dated March 18, 2009). Dr. Metzlaff testified in his written declaration that "Flavell, Metzlaff et al. and Stam et al (or other contemporaneous publications related to the field of co-suppression) did not contemplate that double stranded RNA structures formed between antisense RNA and the sense mRNA could be a triggering agent in gene silencing." (Metzlaff Decl. ¶ 9.) Rather, Dr. Metzlaff testified that a person of ordinary skill in the art "understanding the proposed models for gene silencing would not have included a sense and antisense RNA strand in one single molecule to obtain more efficient self annealing." (Metzlaff Decl. ¶ 9.) Dr. Metzlaff explained "the proposed models and

prevailing wisdom considered a[n] antisense strand to be the operative gene-silencing triggering molecule." (Metzlaff Decl. ¶ 9.) Dr. Metzlaff supported his expert opinion with factual evidence from the scientific literature, describing four prevailing hypotheses (Metzlaff Decl. ¶ 17-21). One of the hypotheses involved the formation of double-stranded RNA, but the duplex was formed from an aberrant mRNA and mRNA from the transgene or normal gene copy (Metzlaff ¶ 20). Consequently, a skilled worker would not have thought that a hairpin structure as claimed would produce gene silencing, as the mRNA in the cell would be unaffected by it. Dr. Metzlaff also provided a detailed discussion of the Flavell, Metzlaff, and Stam, providing factual support for his opinion that there were errors in the Examiner's analysis (Metzlaff 26-31).

We independently have reviewed Flavell, Metzlaff, and Stam, and find their disclosures fully consistent with Dr. Metzlaff's opinion and supporting facts. As Dr. Metzlaff testified, the duplex described in the prior art publications involved the endogenously produced RNA of the silenced genes. The following factual evidence supports Dr. Meltzaff's testimony:

• Flavell describes the formation of double-stranded duplex RNA between endogenous mRNA and antisense RNA as one possible mechanism of gene silencing observed during co-suppression (Flavell 3492-3993).

• Flavell describes inverted repeats in the DNA of transformed plants during co-suppression, but does not appear to describe an RNA based mechanism for their gene silencing activity (Flavell 3493, col. 1, section (i)).

• Metzlaff describes a model of gene silencing "based on RNA-RNA base pairing" (Metzlaff 845). The base-pairing referred to by Metzlaff appears to between sequences in the endogenous mRNA produced by the

endogenous or transgene and aberrant RNA, where the thus formed duplexes are degraded by enzymes resulting in degradation of the mRNA (Metzlaff 851, col. 2, second paragraph; 852, Figure 2 & col. 1-2).

• Stam describes a model for gene silencing in plants. In one pathway, Stam describes mRNA degradation as the reason for the gene silencing (Stam 4, Figure 1, right-side). Stam states that "[w]e can only speculate about the nature of this RNA degradation activity." (Stam 8, col. 1, 3rd full-paragraph.) Stam states that in this pathway it "is hypothesized that in vivo these cRNAs [antisense RNA produced by aberrant RNA processing in the cell] hybridize to complementary mRNAs which are then degraded by double-stranded RNA specific RNases." (Stam 8, col. 1, 3rd full-paragraph.)

• Stam describes inverted repeats in the genomic DNA of transgenic plants, but describes them as producing aberrant RNAs that cause degradation of endogenous mRNA or involving methylation activity (Stam 8, col. 2).

Accordingly, as all the silencing duplex structures involved endogenous mRNA, a person of ordinary skill in the art would not have been prompted to make a DNA with sense and antisense nucleotide regions capable of forming a hairpin structure. Thus, while the Examiner asserts that "the role of inverted repeats, and other double stranded RNA structures were pondered by those looking for underlying mechanisms of target gene suppression in eukaryotes" (Answer 45), a construct with the claimed sense and antisense sequences would not have been the logical and reasonable choice because the mechanism hypothesized in Flavell, Metzlaff, and Stam involved base pairing with an endogenous sequence and is therefore fundamentally different than the one embodied by the claimed construct.

For the foregoing reasons, we reverse the rejection.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The Examiner provisionally rejected claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109, and 115-122 on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 35-38 of copending Application No. 11/841,737. The Examiner found that the "claims of the instant invention also include the presence of an intron within the recombinant expression constructs, whereas the claims of copending Application No. 11/841,737 do not include introns in the recombinant constructs." (Answer 26.) The Examiner, in setting forth the basis of the obviousness rejections, gave reasons as to why intron sequences would be routinely incorporated into recombinant constructs, e.g., to enhance vector stability, as evidenced by Brown and Lusky (Answer 45).

Appellant contends that Lusky and Brown do not remedy the deficiencies of Flavell, Metzlaff, and Stam (App. Br. 42), that the intron teachings are not pertinent to double-stranded RNA silencing with the claimed hairpin structure (App. Br. 35 & 36), and the mechanisms as to why introns enhanced gene silencing were unknown and unpredictable (App. Br. 36).

These arguments are not persuasive. The Examiner provided evidence that introns enhanced stability and expression of nucleic acids in an expression construct (Answer 12 & 22). Appellants did not provide adequate scientific reasoning or factual evidence as to why the claimed chimeric DNA would have been expected to behave any differently due to the presence of a DNA region capable of forming a hairpin structure.

Appellants cite Smith et al. as establishing that inclusion of an intron produces "surprising unpredicted improvement in the invention." (App. Br. 36.) Appellants contend:

> These findings were published in the scientific literature by the inventors in Smith et al., *Nature,* 407:319-32, 2000 (EXHIBIT 9). The improved efficiency provided by the inclusion of an intron in the construct was not predicted or predictable. However, the improvement has been widely adopted in the art since the publication of Smith et al.

(App. Br. 36.)

However, unexpected results must also be "commensurate in scope with the degree of protection sought by the claimed subject matter." *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005). Appellants did not establish that the results shown in Smith et al. were commensurate with the full scope of the independent claims. Appellants also did not show that the stated improvement was widely adopted because of the intron, rather than another feature of the constructs utilized in the Smith et al. publication. "For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

For the forgoing reasons, we affirm the Examiner's provisional rejection of claims 22, 26, 42, 53, 54, 56, 58, 63-69, 100-103, 109, and 115-122 on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 35-38 of copending Application No. 11/841,737.

SUMMARY

We reverse Rejections 1-3, but affirm Rejection 4.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

KMF